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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,577	07/19/2005	Takanori Uchida	UCHIDA9	6886
1444 7590 06/01/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/542,577		UCHIDA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Taeyoon Kim		1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 14-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-6 and 14-35 are pending.

#### ***Response to Amendment***

Applicant's amendment and response filed on Feb. 28, 2007 has been received and entered into the case.

Claims 7-13 are canceled and claim 35 is newly added. Claims 1-6 and 14-35 are pending and have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. §112, second paragraph, is now withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §102(b) based on Greenawalt et al. is withdrawn due to the amendment.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on Feb. 28, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/534,715 has been reviewed and is accepted. The terminal disclaimer has been recorded.

However, due to the amendment made to claims 14-16, which now includes the subject matter of "fibrinogen" in the method disclosed, the provisional rejection based on obviousness-type double patenting is now withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 14-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenawalt et al. (US 6,056,970) in light of Geller et al. (1971) and Ikada et al. (US 4,882,162).

Claims 1-6 and 21-35 are drawn to a hemostatic material or a kit comprising thrombin and fibrinogen on a bioabsorbable synthetic nonwoven fabric (claims 1, 21 and 29); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claims 2, 22 and 30); the material being polyglycolic acid (claims 3, 23 and 31); a limitation to the bioabsorbable synthetic nonwoven fabric

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pretreated with thrombin and then fibrinogen (claim 4); a limitation to the hemostatic material or kit comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride (claims 5, 24 and 32); the additive being calcium chloride (claim 25); the additive being Factor XIII in a container comprising fibrinogen (claims 26 and 33); a limitation to thrombin and fibrinogen being derived from human blood or produced by a genetic recombinant technique (claims 6, 27 and 34); a hemostatic kit comprising a bioabsorbable synthetic nonwoven fabric holding thrombin being made by the method of claim 14 (claim 28); a limitation to the hemostatic material being in the form of sheet having sufficient flexibility and elasticity to stick area with any shape (claim 35).

Claims 14-20 are drawn to a method of preparing a bioabsorbable synthetic nonwoven fabric by the steps of immersing a bioabsorbable synthetic nonwoven fabric into a solution containing thrombin and lyophilizing the obtained nonwoven fabric, and then applying fibrinogen (claim 14); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claim 15); the material being polyglycolic acid (claim 16); a limitation to the hemostatic material comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride (claim 17); calcium chloride of claim 17 being fixed to the bioabsorbable synthetic nonwoven fabric with thrombin (claim 18); Factor XIII being added to fibrinogen (claim 19); thrombin, fibrinogen and Factor XIII being derived from human blood or a produced by a genetic recombinant technique (claim 20).

Greenawalt et al. teach a composition, a method and a kit comprising hemostatic compounds such as thrombin, fibrinogen, Factor XIII, protease inhibitors and calcium chloride, along with a bioabsorbable synthetic polymer (nonwoven fabric) made of polyglycolide (polyglycolic acid), polylactide (polylactic acid) or copolymers thereof (columns 2-4).

Greenawalt et al. also teach thrombin and fibrinogen are derived from human plasma or synthetic forms produce by recombinant DNA technology (column 3, lines 52-64).

Greenawalt et al. also teach the bioabsorbable fabric containing thrombin and fibrinogen is made by mixing thrombin, fibrinogen and bioabsorbable polymers in organic solvent and then drying (lyophilizing) the combination (column 5, lines 5-11 and 29-46).

Greenawalt et al. teach a hemostatic kit containing multiple hemostatic compositions in a separate package (column 6, lines 51-55).

Greenawalt et al. also teach the composition can include other components to provide stability, strength and flexibility (see column 15, lines 25-27).

Although Greenawalt et al. do not teach a process of forming the nonwoven fabric comprising thrombin and fibrinogen, wherein the fabric being treated with thrombin first and then treated with fibrinogen (claim 4), it would have been obvious for a person of ordinary skill in the art to modify the order in applying thrombin and fibrinogen to the fabric formed in the method. In fact, the method of Greenawalt et al., which utilizes a mixture of thrombin and fibrinogen along with cellulose fiber (CMC pulp)

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and/or biocompatible polymer (PGA fiber), would result in layers with a mixture of different orders (e.g. fiber/thrombin/fibrinogen and fiber/fibrinogen/thrombin).

Furthermore, since Greenawalt et al's product appears to be effective as a hemostatic, the order of thrombin and fibrinogen applied to the composition would be considered not to affect their functionality.

M.P.E.P. § 2144 recites, "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law...If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." In *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. In *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), the court found that selection of any order of mixing ingredients is *prima facie* obvious. Since it would have been obvious to perform process steps in any order, the product of the method, which comprises thrombin and fibrinogen, would have any order of thrombin and fibrinogen layers applied to the fabric.

Although Greenawalt et al's product is described as "paper-like material," it is mainly made of carboxymethylcellulose (CMC) pulp (cellulose fiber) and/or polyglycolic acid (PGA) (see Examples), which would provide sufficient elasticity and flexibility as evidenced by Geller et al. (1971) and Ikada et al. (US 4,882,162). Therefore, the



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product of Greenawalt et al. would have inherent elasticity and flexibility to be formed into any shape. Unless applicant provides clear evidence that the composition of Greenawalt et al. does not possess the same elasticity and flexibility of the claimed invention, the examiner takes the position that the product of Greenawalt et al. would have the same property as the current invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made especially in the absence of evidence to the contrary.

Applicant argued that the reference (Greenawalt et al.) does not teach the use of a material in the form of nonwoven fabric. The examiner respectfully disagrees with the assertion. Greenawalt et al. teach a method using forming fabric to collect the fibrous pulp made of carboxymethylcellulose and/or polyglycolic acid for the material used in the component (see column 5, lines 29-39). Although Greenawalt et al. is silent whether the fibrous pulp material is a woven or nonwoven material, the process for the material of Greenawalt et al. (collecting fibrous pulp, pressing and drying to make cellulose fiber) is inherently producing a fibrous pulp based nonwoven material.

Applicant also argued that the reference (Greenawalt et al.) teaches to use an organic solvent and one example of organic solvent being carbon tetrachloride. The examiner agrees that Greenawalt et al. disclose a method using an organic solvent and carbon tetrachloride being one example. However, as all the examples in the specification in Greenawalt et al. utilize ethanol as an organic solvent, and it is well known that carbon tetrachloride is toxic and ozone-depleting gas (greenhouse gas), it



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would have been obvious for a person of ordinary skill in the art not to use toxic organic solvents such as carbon tetrachloride, and use ethanol instead. Upon the drying step of the method taught by Greenawalt et al., ethanol would be completely evaporated and there would be no residual ethanol remained in the product.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

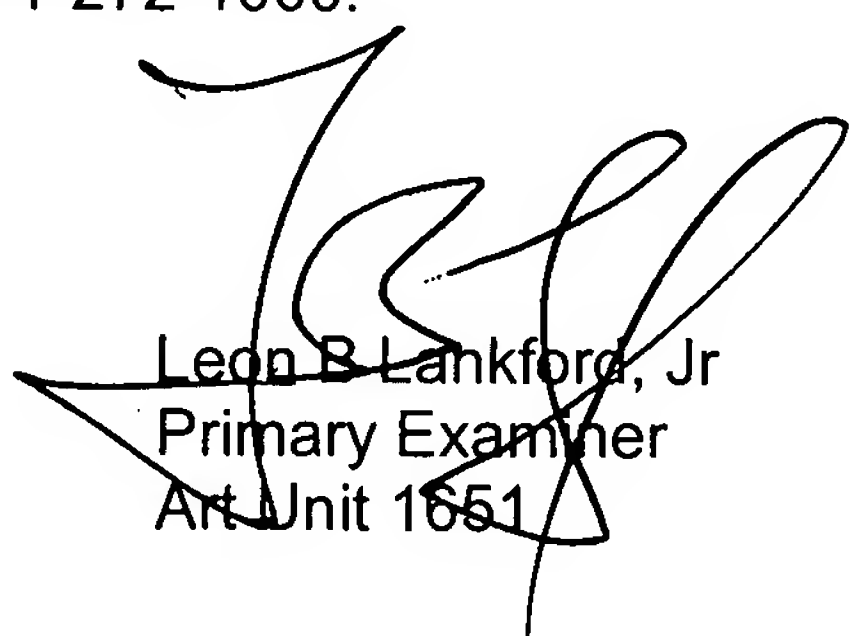
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim  
Patent Examiner  
Art Unit 1651



Leon B. Lankford, Jr.  
Primary Examiner  
Art Unit 1651